Z1907: A Phase I Study of Infused Mobilized, Autologous Peripheral Blood Progenitor Cells, which Have Been Incubated with a Recombinant Adenovirus-Wild-Type p53(SCH 58500) Construct to Purge any Contaminating Breast Cancer Cells, as Stem Cell Support after High-Dose Chemotherapy in Patients with Breast Cancer Metastatic to Bone and Bone Marrow.

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Scientific Abstract

Preliminary data have indicated that a recombinant adenovirus wild type P53 gene construct (SCH 58500) is capable of selectively targeting and eliminating breast cancer cells while having no effect on hematopoietic progenitor cells. This property is attractive for the purposes of eliminating contaminating cancer cells from hematopoietic progenitor cells collected as a prelude to autologous transplantation in breast cancer. This study will evaluate the safety of incubating peripheral blood progenitor cells products, collected from patients with breast cancer metastatic to bone or bone marrow, with three increasing concentrations of the SCH 58500. All patients will also store a backup product. Safety will be assessed by infusing the purged product as the stem cell rescue. Safety parameters will include evaluation of adverse events, infusion reactions, neutrophil and platelet engraftment, the development of construct related adenoviral infection. Failure to engraft will necessitate use of the stored backup product. Secondary endpoints will include evaluation of the efficacy of cancer cell purging. The measurements will include the quantitation of cancer cells before and after incubation with SCH 58500 along with specific measure of apoptosis. In addition we will evaluate the development of adenoviral immunity as well as immune reconstitution post transplant.